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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/955,485      | 09/19/2001  | Michael A. Moskowitz | 031695.0031         | 7759             |

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

|   |                                       |   |
|---|---------------------------------------|---|
| <b>Office Action Summary</b>  | Application No.<br><b>09/955,485</b>  | Applicant(s)<br><b>Moskowitz et al.</b> |
|   | Examiner<br><b>Phyllis G. Spivack</b> | Art Unit<br><b>1614</b>                 |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>  |                                       |   |
| <b>Period for Reply</b>   |                                       |   |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  |                                       |   |
| - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.<br>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.<br>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.<br>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).<br>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                       |   |
| <b>Status</b>   |                                       |   |
| 1) <input type="checkbox"/> Responsive to communication(s) filed on _____.  |                                       |   |
| 2a) <input type="checkbox"/> This action is <b>FINAL</b> .      2b) <input checked="" type="checkbox"/> This action is non-final.   |                                       |   |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.   |                                       |   |
| <b>Disposition of Claims</b>  |                                       |   |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>20-35</u> is/are pending in the application.   |                                       |   |
| 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.   |                                       |   |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed.  |                                       |   |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>20, 21, 23, 24, and 28-35</u> is/are rejected.   |                                       |   |
| 7) <input checked="" type="checkbox"/> Claim(s) <u>22 and 25-27</u> is/are objected to.   |                                       |   |
| 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.  |                                       |   |
| <b>Application Papers</b>   |                                       |   |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner.   |                                       |   |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.<br>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                                       |   |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.<br>If approved, corrected drawings are required in reply to this Office action.   |                                       |   |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.  |                                       |   |
| <b>Priority under 35 U.S.C. §§ 119 and 120</b>  |                                       |   |
| 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                                       |   |
| a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:<br>1. <input type="checkbox"/> Certified copies of the priority documents have been received.<br>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.<br>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).   |                                       |   |
| *See the attached detailed Office action for a list of the certified copies not received.   |                                       |   |
| 14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).<br>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.  |                                       |   |
| 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |                                       |   |
| <b>Attachment(s)</b>  |                                       |   |
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   |                                       |   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  |                                       |   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____   |                                       |   |
| 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |                                       |   |
| 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)   |                                       |   |
| 6) <input type="checkbox"/> Other: _____  |                                       |   |

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A Preliminary Amendment filed September 19, 2001, Paper No. 1 1/2, is acknowledged. Claims 1-19 are canceled. New claims 20-35 are presented and represent all of the claims under consideration.

The undersigned Examiner supports the goal of the Office to advance prosecution as expeditiously as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 21 23, 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myslivecek et al., Neuroscience (abstract).

Myslivecek teaches the substantially contemporaneous administration of an NO-increasing agent, L-arginine, with a physiologically active composition comprising dopamine, in the brain. The claims differ in that Myslivecek does not specifically recite an increase in cerebral bioavailability of the physiologically active agent dopamine. However, one skilled in the neurology art would have reasonably considered an improvement in learning and memory processing to have been the result of an increase in cerebral bioavailability of dopamine and NO.

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Such would have been obvious because Myslivecek teaches a dose dependent enhancement of learning and memory suggesting an increase in cerebral bioavailability of dopamine and NO.

Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al., Proceedings of the Society for Experimental Biology and Medicine (abstract).

*Myslivecek*  
Werner teaches the requirement of various cofactors for the enzymes nitric oxide synthases. In order for the conversion of L-arginine to nitric oxide to take place, NADPH and tetrahydrobiopterin are required. Werner fails to recite a composition comprising an NO-increasing agent or agents and at least one physiologically active. However, intended use of a composition confers no patentable weight to the composition claim. One skilled in the art would have been motivated to prepare a composition comprising the NO-increasing agent or agents with various other physiologically active agents in view of Werner's teaching. Such would have been obvious in the absence of evidence to the contrary because where the desirability of synthesizing nitric oxide is sought, Werner suggests the combination of L-arginine with various physiologically active cofactors.

Claim 35 is objected to under 37 CAR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 35, directed to a site of action, does not further limit the subject matter of composition claims 29 or 30.

No claim is allowed.

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Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

November 26, 2002

*Phyllis Spivack*

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**